PlumePen® Elite

Surgical Plume Evacuation Pencil

If you have any questions or need any assistance with the set-up or use of the PlumePen® Elite Surgical Plume Evacuation Pencil please contact Buffalo Filter® at:
U.S. toll-free: 800.343.2324
International: 1.716.835.7000
Email: smoke-info@buffalofilter.com

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Indications For Use: The **PlumePen® Elite** is designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Indications for Use for the **PlumePen® Elite** Integrated Smoke Evacuation Pencil include:

a. To remove smoke plume from the surgical site.

b. To remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect.

Figure 1.
Open product packaging and remove the **PlumePen® Elite** Surgical Plume Evacuation Pencil assembly. Connect the tubing provided with the **PlumePen® Elite** to a smoke evacuation system or other appropriate vacuum source; example shown, (Figure 1). For connection and operation to a specific smoke evacuation system, please refer to the specific instructions for use for appropriate setup and use.

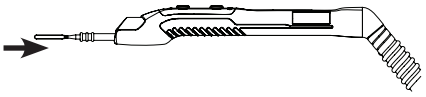

Figure 2.
Prior to connecting the **PlumePen® Elite** 3-prong power cord to the electro-surgical generator, ensure that the electrode blade (provided) is fully inserted into the pencil by gently pressing it in front of the **PlumePen® Elite** . Remove the plastic shield from the blade and discard.

Figure 3.
Plug the 3-prong power cord into the electrosurgical generator of your choice, (Figure 3). Confirm that all power settings on the generator are appropriate for the procedure being performed. The electrosurgical generator's intensity should be set as low as isnecessary to achieve the desired effect. The **PlumePen® Elite** is a monopolar electrode, the use of a dispersive electrode is required to prevent burns/injury to patient. Please refer to electrosurgical generator user manual and dispersive electrode instructions for use for additional instructions.

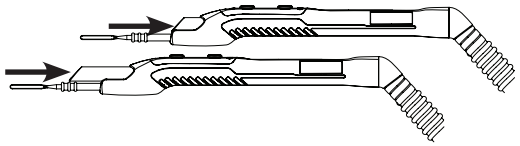

Figure 4.
The **PlumePen® Elite** is equipped with several key features for the surgeon's convenience. Above the electrode blade is a translucent plastic tube that can be positioned at varying lengths, (Figure 4) to most effectively capture surgical smoke plume as it is created.

With the electrosurgical generator off and the electrode blade cool, position this tube as near the point of the tissue interaction as possible without obstructing the view of the target tissue.

Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.

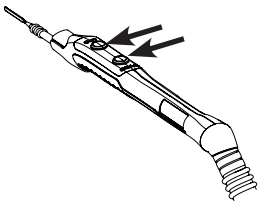

Figure 5.
The **PlumePen® Elite** has CUT and COAG buttons located on the top of the electrosurgical pencil body. The YELLOW button is for cutting and the BLUE button is for coagulation, (Figure 5).

After use, turn off smoke evacuation unit and electrosurgical generator. Discard the entire **PlumePen® Elite** assembly (Pencil, Blade, Tubing, and Power Cord) per facility protocol for contaminated items.

Figure 6.
To optimize the life of your smoke evacuation filter, it is recommended that a Buffalo Filter Surgical Smoke Plume Evacuator be used in conjunction with an EZLink™ Automatic Activation Device (Model EZLink01), (Figure 6).

The EZLink™ will automatically turn the Buffalo Filter Surgical Smoke Plume Evacuator on or turn it off when either the CUT or COAG function is activated/ de-activated on the **PlumePen® Elite** . Contact Buffalo Filter® for more details on the EZLink™.

CAUTION:

DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

INSPECT instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.

Sterility unless packaging is damaged or any seal is broken. Do not use electrosurgery in the presence of flammable anesthetics or other flammable gases, fluids, or objects, or in the presence of oxidizing agents, as fire may result. Place active accessories in a holster or in a clean, dry, non-conductive and highly visible area away from the patient when not in use. Inadvertent contact with the patient may result in burns. Contact with drapes or linens may cause a fire.

DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling.

PlumePen® Elite is designed and intended only to be used with an electrosurgical generator that has been tested to the IEC 60601 standard. Please refer to generator to ensure compatibility. PlumePen® Elite is not a fluid removal device, therefore, it should not be used for such application.

ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.

Buffalo Filter recommends that the original blade be utilized with the PlumePen Elite.

If original blade is removed, visually confirm new blade is completely inserted and secured before activating the pencil. Never force the blade into the pencil. Rotate the pencil if the smoke tube is obstructing view of the insertion point.

For procedures where visualization may be impaired, be alert of these potential hazards:

- **The electrode tip may remain hot enough to cause burns after the current has been de-activated.**
- **Inadvertent activation or movement of the activated electrode outside of the field of vision may result in injury to the patient.**
- **Localized burns to the patient or physician may result from electrical currents carried through conductive objects. Current may be generated in conductive objects by direct contact with the active electrode, or by the active accessory being in close proximity to the conductive object.**

For single use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness, or death.

This single-use product is not designed or validated to be reused. Reuse may cause a risk of cross-contamination or cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization, or reuse.

BUFFALO Filter

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www.buffalofilter.com

Do Not Use Damaged

Single Use Only Do Not Reuse

c UL us

Does Not Contain Natural Rubber Latex

Do Not Resterilize

STERILE R

CAUTION:
Intended for use with a maximum voltage of 10kV P-P.

Rx ONLY

REF **PLP1001 PLP2001 PLP1501 PLP2501**